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SYSTEMS FOR DIAGNOSTIC TESTING

5 The present invention relates generally to systems for use in diagnostic testing.

In the medical arena, diagnostic testing is frequently performed to determine if a particular medical condition is present in a given patient. Diagnostic testing systems, which may be referred to as test kits, are manufactured to test for a wide variety of conditions in numerous types of biological test specimens, such as, for example, blood, tissue biopsies, and saliva. Such testing systems may be utilized to determine the presence of particular bacteria, such as *Helicobacter pylori*. Some tests that have been proposed to detect *Helicobacter pylori* include those that are disclosed in numerous U.S. Patents, including, for example, U.S. Patent No. 4,748,113 to Marshall, U.S. Patent No. 5,314,804 to Boguslaski et al., U.S. Patent No. 5,439,801 to Jackson, U.S. Patent No. 5,702,911 to Whalen, U.S. Patent No. 5,989,840 to D'Angelo et al., U.S. Patent No. 6,068,985 to Cripps et al., U.S. Patent No. 6,156,346 to Chen et al., and U.S. Patent No. 6,187,556 to Lee et al., each of such patents being incorporated in their entirety by reference herein.

20 Various embodiments of the present invention are directed to a diagnostic system for diagnostic testing having a carrier having a first well and a second well. A specimen-handling tool may be disposed about at least a portion of one of the wells. The specimen-handling tool may be disposed within a cavity formed in the

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carrier. The specimen-handling tool may be adapted to manipulate a specimen such as a biopsy sample. An overlying member may be provided and may be disposed adjacent to the top surface of the carrier. The overlying member may be positioned over at least a portion of one or more of the wells and/or the cavity.

- 5 The specimen-handling tool may include a pair of cooperating arms. Each arm may include a tip portion and a rear portion, the arms being joined to each other at their rear portions. Each arm may further include a rearward arcuate portion, a forward arcuate portion, and an intermediate arcuate portion that is disposed between the rearward arcuate portion and the forward arcuate portion.
- 10 The arcuate portions may be configured so that the area disposed between the pair of arms is approximately hourglass in shape.

Figure 1 is a perspective view of an embodiment of the system, carrier and specimen-handling tool of the present invention.

- 15 Figure 2 is a perspective view of an embodiment of the carrier of the present invention.

- 20 Figure 3 is a perspective view of the bottom of an embodiment of the carrier of the present invention.

Figure 4 is a side view of an embodiment of the carrier of the present invention.

- 25 Figure 5 is a top view of another embodiment of the carrier of the present invention.

Figure 6 is a perspective view of an embodiment of the specimen-handling tool of the present invention.

- 30 Figure 7 is a side view of an embodiment of the specimen-handling tool of the present invention depicted in Figure 6.

Figure 8 is another perspective view of an embodiment of the specimen-handling tool of the present invention.

Figure 9 is a top view of the embodiment of the specimen-handling tool of the present invention that is depicted in Figure 8.

Figure 10 is a perspective view of yet another embodiment of the specimen-handling tool of the present invention.

Figure 11 is a perspective view of still another embodiment of the specimen-handling tool of the present invention.

Figure 12 is a perspective view of another embodiment of the system, carrier and specimen-handling tool of the present invention.

Figure 13 is a cross-sectional view of the embodiment depicted in Figure 12, taken along line 13-13.

Figure 14 is a perspective cross-sectional view of the embodiment depicted in Figure 12, taken along line 14-14.

Figure 15 is a perspective view of another embodiment of the system of the present invention.

Figure 16 is a cross-sectional view of the embodiment depicted in Figure 15, taken along line 16-16.

Figure 17 is a perspective view of yet another embodiment of the specimen-handling tool of the present invention.

Figure 1 discloses an embodiment of a diagnostic system 20 according to the present invention that may be utilized for many types of diagnostic testing. Such diagnostic tests utilize a biological test specimen such as, for example,